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MCCRACKEN & FRANK LLP
311 S. WACKER DRIVE
SUITE 2500
CHICAGO, IL 60606

EXAMINER	
LEUBECKER, JOHN P	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/677,874	**Applicant(s)** MALACKOWSKI ET AL.	
	Examiner John P. Leubecker	**Art Unit** 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2003*.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-79* is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *35-79* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on *02 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date *1/23/04, 5/22/08 & 9/15/08*.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Specification

1. The disclosure is objected to because of the following informalities: on page 1, the first sentence (as amended on October 2, 2003) should be amended to include the status of the parent application (abandoned).

Appropriate correction is required.

2. The abstract of the disclosure is objected to because it only sets forth that which is known in the art (note page 1, lines 18-25 of the specification). Correction is required. See MPEP § 608.01(b).

Claim Objections

3. Claims 40, 42, 50, 59, 60, 75 and 76 are objected to because of the following informalities: As to claim 40, line 2, "used" should be –uses--; As to claim 42, line 2, "camera" should be –cameras--; As to claim 50, line 2, "assembly" should be –system--; As to claim 59, "infrared" should be inserted between "of" and "light" in line 3 to be consistent with the last line of the claim; As to claim 60, line 2, "the relation positions" should be –the relative positions--; As to claim 75, line 7, "tot" should be –to—and in line 8, "tool" should be –instrument--; As to claim 76, line 5, "f" should be --of--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

> pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 55-62 and 77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a) Regarding claims 55-62, the specification explicitly provides a universal tracker device (200) as part of the patient tracking system (502) (note page 11, line 23 to page 12, line 14 of the specification). Thus, regarding claims 55, 58 and 62 (which effects dependent claims thereof), the specification fails to disclose a patient tracking system including a universal tracker device and an additional universal tracker device "coupled to the patient tracking system".

b) Regarding claim 77, the specification fails mention the function of performing “a surface matching operation with a known contour”. Although the specification mentions that markers (3304) “can be used by the system 100 for surface matching” and “can be used to register that tracked feature of the patient to an image data set, e.g., a CT scan, using for example, surface matching techniques", no mention of contour matching, what is encompassed by "a known contour”, or any insight as to what structure/programs is required to perform such feature is provide.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 42, 43, 49, 55-62, 74, 75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 42, term “sensor array” lacks antecedent basis.

As to claim 43, this claim is a substantial duplicate of claim 42.

As to claim 49, recitation of "is a graphic" is indefinite as to what this is referring.

As to claims 55, 58 and 62, recitation of both a “patient tracking system” and a “universal tracker device coupled to the patient tracking system” makes these claims indefinite as to what exactly is intended to be encompassed by “patient tracking system” since the specification explicitly states that a universal tracker device is incorporated into such "patient tracking system".

As to claim 74, line 10, term “calibration tool” lacks antecedent basis.

As to claim 75, line 3, term “the validation tool” lacks antecedent basis. In lines 12 and 13, term “calibration station” lack antecedent basis.

Dependent claims where present inherit those defects.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 35, 41, 44-47, 49, 50, 55-58, 62-68, and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Chader et al. (U.S. Pat. 5,617,857).

As to claim 35, and referring to Figure 1, Chader et al. disclose at least one smart instrument (12), a computer system (14,18,28), and a sensor system (16) adapted to wirelessly sense the position of the at least one smart instrument (col.5, lines 35-42) and to transmit position information to the computer system (col.5, lines 48-67).

As to claim 41, the sensory system includes a sensor array (note plurality of sensors 22, Fig.1).

As to claims 44-47 and 49, the computer system includes a monitor (28) which is capable of displaying an image of a patient and a representation (graphic) of the instrument (col.5, line 62 to col.6, line 2).

As to claim 50, the computer system includes a localizer (14), a computer workstation (18) and a monitor (28).

As to claims 55-57, Chader further includes a patient tracking system (reference frame 24), a universal tracker device (26) coupled to the patient tracking system and including a validation point (col.9, lines 55-67). The sensor system is capable of wirelessly sensing the position of the universal tracker device and transmit position information to the computer system (col.5, lines 59-62).

As to claim 58, all elements of this claim have been previously set forth above with respect to claims 35, 50 and 55.

As to claim 62, all elements of this claim have been previously set forth above with respect to claims 35, 50, 55 and 56.

As to claims 63-68, Chader et al. discloses that more than one instrument (32, Fig.3) can be used (col.7, lines 49-52). Other limitations in these claims are discussed above.

As to claim 79, the structure as described above also includes at least one button (46, col.7, lines 8-11). The read switch control (48, Fig.2) can transmit status information (e.g., on/off) of the button and the computer is capable of performing an operation in response to said button (col.7, lines 11-16).

10. Claims 72-75 are rejected under 35 U.S.C. 102(e) as being anticipated by Moctezuma (U.S. Pat. 6,306,126).

Moctezuma disclose at least one smart instrument (col.4, lines 58-60); a validation/calibration tool, the validation/calibration tool including: a base (10,42); four columns (14a-14d) coupled to the base; at least one validation point (any point could be a "validation point" but note plate 12); and a plurality of infrared light emitting diodes (46) coupled to the base; an upper plate (16) and a lower plate (18) slidably coupled to the four columns (col.4, lines 24-31), the upper and lower plates each including an aperture (28) for receiving the smart instrument; a computer system (col.5, lines 16-17); a sensor system (col.4, lines 43-44) adapted to wirelessly sense the position of the at least one smart instrument and the calibration tool and to transmit position information to the computer system (col.5, lines 16-28).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chader et al. in view of Acker et al. (U.S. Pat. 6,453,190).

Chader et al. disclose the device as described above and further includes a memory circuit (36,Fig.2) for storing information related to the smart instrument (col.6, lines 18-25). The instrument is adapted to transmit the information to the computer system with wires (see Fig.2) and thus is not shown to be adapted to wirelessly transmit such information. Acker et al. discloses an analogous tracking system (note Abstract) and explicitly teaches that although the connection between the instrument and the computer uses wires, such wires can be replaced by a wireless connection (col.11, line 61 to col.12, line 4). Acker et al. further explicitly teaches that such use of a wireless connection avoids "the physical encumbrance of loose wires trailing from the instrument" (col.12, lines 3-4). In view of this teaching regarding a directly analogous portion of the Chader et al. reference, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided a wireless connection in place of the wired connection of Chader et al.

As to claim 37, the information in the memory circuit of Chader et al. is calibration information (e.g., col.6, lines 35-44).

13. Claims 38, 39, 48, 51-54 and 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chader et al. in view of Simon et al. (US 2003/0073901).

As to claims 38 and 39, Chader et al. disclose the device as described above wherein the energy emitting elements (20) can be LEDs (and other suitable elements, col.6, lines 64-66) but does not disclose any particular wavelength for the sensor system (16) to detect. Thus, Chader fails to disclose that the LEDs emit infrared wavelengths (which would mean the sensor system would detect infrared wavelengths) or that the emitters/sensors use radio frequency signals. Simon et al. teach a similar position tracking system which uses an infrared tracking sensor to sense infrared LEDs (note numbered paragraphs [0004] and [0053]). Simon et al. also explicitly teaches that other kinds of energy emitter/sensor arrangements could be used including radio waves ([0053]). Since both reference to Chader et al. and Simon et al. teach position tracking systems, it would have been obvious to one of ordinary skill in the art to have substituted one form of emitter/sensor arrangement for another to achieve the predictable result of providing a positional location of a tracked object.

Further as to claims 51-54, no matter what form of emitter/sensor arrangement is used, Chader et al. disclose that the localizer (14) is adapted to receive position information from the sensor system, determine the relative positions of each of the plurality of infrared LEDs and transmit the positions to the computer (col.5, lines 38-42 and 55-65).

In addition, regarding claims 59-61, the universal tracker (26) includes the same energy emitting elements as the instrument is tracked in the same way as the instrument(col.5, lines 42-47 and 59-62).

As to claim 48, Chader et al. disclose the device as set forth above including a 'position marker' on the screen but fails to specify that the marker is a line. Although any 'position marker' forming a representational graphic on the screen could be considered as including at least one 'line', Simon et al. disclose a representation in the form of a line (note 502, Fig.5A). It would have been obvious to one of ordinary skill in the art to have used what is known in the art for representing a surgical instrument on the screen, including a line as taught by Simon et al.

14. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chader et al. in view of Simon et al., as set forth immediately above, and further in view of Brown et al. (U.S. Pat. 6,366,622).

Chader et al., as modified by Simon et al. above, disclose use of radio waves (rf) but fails to disclose any frequency range or wireless standard. Brown et al. teaches that the IEEE 802.11 is a standard used in the ISM radio frequency band (col.21, lines 30-37). The IEEE 802.11 standard is known radio frequency standard in the ISM band, which is free for all to use. It would have been obvious to one of ordinary skill in the art to have used any known radio frequency standard, and particularly one that is free for all to use.

15. Claims 69-71 and 76-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chader et al. in view of Acker et al. (U.S. Pat. 5,752,513).

Chader et al. is described above with respect to the smart instrument, computer system and sensor system. Chader et al. discloses a frame (24) and what looks like a band (Fig.1) to secure the reference markers with respect to the patient. Acker et al. discloses a similar tracking system in which the reference markers (96, col.7, lines 53-57) can secured to the patient by a band or strap, but could also include conventional surgical adhesive tape (col.7, lines 57-64). Since both Chader et al. and Acker et al. teach systems in which markers are secured to the body, it would have been obvious to substitute one fastening means for another to achieve the predictable result of securing the markers to the body. Use of a surgical adhesive tape would anticipate a sheet of flexible mesh material having markers on a first side and a layer of adhesive on the other side.

As to claims 76-78, considering the adhesive tape with the LED markers on it (as described immediately above) as the “smart instrument”, the claim is obvious for the reasons set forth above. It is noted that since the computer of Chader et al. can determine locations of the LEDs, determining such locations in 3D space on the flexible tape would inherently result in a contour. In addition, since Applicant's only structure for being “adapted to determine the contour of the smart instrument and perform a surface matching operation with a known contour" is a computer, the computer of Chader et al. is considered as being capable of performing such function. As to claim 79, since the flexible tape can move and still be detected, it is considered a dynamic reference frame.

Allowable Subject Matter

16. Claim 42 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 7217276 B2	Henderson; Jaimie et al.
US 6697664 B2	Kienzle III; Thomas C. et al.
US 6675040 B1	Cosman; Eric R.
US 6618612 B1	Acker; David E. et al.
US 6405072 B1	Cosman; Eric R.
US 5987960 A	Messner; Dale A. et al.
US 6226548 B1	Foley; Kevin T. et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Leubecker whose telephone number is (571) 272-4769. The examiner can normally be reached on Monday through Friday, 6:00 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John P. Leubecker/
Primary Examiner
Art Unit 3739

jpl